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VIA CM/ECF

The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building
& U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101

Re: ***In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*., U.S. District Court for the District of New Jersey; Case No. 1:19-md-02875-RBK-JS**

Dear Judge Schneider:

On behalf of the Teva Defendants, we write to notify the Court that despite a good faith attempt to negotiate a validation protocol with Plaintiffs' counsel over the past several days, including significant time and effort spent over the weekend by all parties including the Court, the Teva Defendants regretfully report that no agreement can be reached on a non-confidential validation protocol that does not contemplate turning over irrelevant documents to Plaintiff. Accordingly, **the Teva Defendants hereby withdraw their Letter Brief in Support of Request to Enforce the ESI Protocol (Dkt. 516), without prejudice to Teva's ability to seek further relief as set forth below.**

Despite the Court's helpful attention and assistance over recent weeks, for which we are extremely thankful, we do not see a path forward for agreement between the parties on a validation protocol that ensures Teva will not be required to produce non-responsive documents to Plaintiffs pursuant to a non-confidential order, other than to withdraw our request. As we have discussed with the Court and counsel in great detail over the recent days, we believe the law is clear (both from the caselaw we've cited to the Court as well as the input of our discovery expert Dr. Maura Grossman) that in utilizing CMML as we've proposed, defendants should not have to turn over non-responsive documents, which undisputedly would not be required in a linear review. *Rio Tinto PLC v. Vale S.A.*, 306 F.R.D. 125, 129 (S.D.N.Y. 2015) ("[I]t is inappropriate to hold TAR to a higher standard than keywords or manual review."); *see also Winfield v. City of New York*, No. 15CV05236LTSKHP, 2017 WL 5664852, at *9 (S.D.N.Y. Nov. 27, 2017) ("[P]erfection in ESI discovery is not required . . . ."); *Aurora Cooperative Elevator Co. v. Aventine Renewable Energy-Aurora West, LLC*, No. 4:12CV230, 2015 WL 10550240, at *2 (D. Neb. Jan. 6, 2015) ("The

[FRCP] rules do not authorize ordering the defendants to disclose irrelevant information."). The risks associated with such a result are too significant, especially given its precedent-setting effect for Teva and potential for disclosure of sensitive material. As a result, Teva is forced to forego its request to use CMML to exclude certain populations of documents to be reviewed at this time. We hope the Court and Counsel can understand Teva's position – while we have full confidence in the CMML platform and its propriety under established law, the balance of benefits shifts if we are required to produce Teva's non-responsive documents and Teva is subjected to a discovery obligation it would not be required to satisfy in a manual review.

Teva has yielded in a significant number of ways in order to satisfy Plaintiffs' concerns, all for naught. As the Court is aware, Teva offered to run CMML over its entire custodial dataset of approximately 8 million documents, has agreed to implement a robust validation protocol with the help of one of the world's leading experts on technology assisted review at its own expense, and provided a draft validation protocol on July 31, 2020 that gives Plaintiffs unprecedented transparency and input into the process. Following our meet and confer on August 1, 2020, the Teva Defendants responded and indicated they were amenable to modifying most, though not all, of the specific areas of the draft protocol that troubled Plaintiffs—other than the disclosure of non-responsive documents. Plaintiffs' response, received Sunday evening and further elaborated upon on August 3rd and 4th makes clear they will not compromise on the threshold issue regarding access to Teva's non-responsive documents, as well as a handful of other positions that Teva and its expert consider unreasonable and unsupported. After significant discussion with and encouragement by the Court, we again conferred with Teva and, on Tuesday, August 4th, proposed a creative and eminently reasonable solution that would allow a third-party discovery vendor to review the proposed validation set, including non-responsive documents, and submit its own report to the Court and the parties. The Court added an additional step – to which Teva did not object – to allow the Court to send certain documents identified by the third-party discovery vendor to Plaintiffs in the event they appeared to be problematic or material in some way. Plaintiffs have yet again unreasonably rejected this proposal. Counsel for Teva attempted one final time this morning to make clear that if Plaintiffs would agree to *either* (1) a confidential order; or (2) a third party neutral vendor receiving and reviewing the audit sample documents (even if these documents could later be provided to Plaintiff after review by the Court), we could come to an agreement. However, Plaintiffs would not consent to either option.

Although there remain several other points of dispute, the fundamental disagreement is that the Teva Defendants cannot agree to a non-confidential validation protocol which permits Plaintiffs to review non-responsive documents, and Plaintiffs will not agree to a validation protocol that does not include this provision in some form.[1] Teva believes when applying proportionality to this issue, the benefit should weigh in its favor. *See Lawson v. Spirit Aerosystems, Inc.*, No. 18-1100-EFM-ADM, 2020 WL 1813395, at *7 (D. Kansas Apr. 9, 2020) (noting in construing TAR issues before the Court that proportionality standard in Rule 26(b)(1) applies to ESI discovery and

[1] Plaintiffs' response to Teva's initial validation protocol also included an unnecessary mandatory review of a certain percentage of documents, removed the concept of "marginal" relevance entirely, gave Plaintiffs nearly unfettered discretion to force the review to continue during the validation process, removed paragraphs of entirely accurate prefatory language intended to protect the parties, contemplated adding additional custodians, and required the Teva Defendants to train the CMML system on tens of thousands of pages of non-custodial documents which had already been produced to Plaintiffs. Despite these unreasonable demands, Teva assented or was able to reach a compromise on each of these issues.

that especially in cases "involving a considerable amount of ESI" proportionality considerations are particularly significant); *Gilmore v. Ford Motor Co.*, Nos. 12-cv-547, 12-cv-548, 2012 WL 12895056, at *3 (W.D. Pa. Dec. 4, 2012) ("[D]iscovery from reasonably accessible ESI sources proceeds in the same manner as discovery from paper sources, and is subject to the burden and proportionality limits of Rule 26(b)(2)(C)); *Fassett v. Sears Holdings Corp.*, 319 F.R.D. 143, 150 (M.D. Pa. 2017) ("Thus, it has been said that the amended [Federal Rule of Civil Procedure 26] restores the proportionality factors to their original place in defining the scope of discovery." (quotation omitted)).

Teva will continue to utilize CMML to prioritize a linear review of its custodial dataset hitting on the search terms set forth in the Court's December 23, 2019 Order (Dkt. 328 at 29-57), as modified by the Stipulated Order Regarding ESI Search Terms Pertaining to the Teva Defendants, (Dkt. 493). As noted previously, given the expansive nature of the search terms, the cost of completing a full linear review will be extremely burdensome and is inconsistent with Teva's obligations under the Federal Rules because the expense will far outweigh the likely benefit from the eyes-on review of millions of documents which CMML indicates are not likely to be responsive, thereby eliminating any element of proportionality from discovery in this litigation. Teva therefore reserves its right to demonstrate subsequently (including providing additional data) that CMML results in the same or better level of recall and precision here than a linear review for a fraction of the cost and to pursue cost shifting, if applicable, moving forward, and/or an order declaring that further review of non-responsive documents is not warranted.

We are very appreciative of the Court's time and efforts to assist the parties in their attempt to reach agreement on Teva's use of CMML to exclude documents at this time and an appropriate validation protocol and truly wish we had been able to reach a reasonable resolution. While we do not expect this letter to change anyone's position, we felt it necessary to put our position on the record, consistent with our discussions over recent days. We recognize this matter took up valuable time and effort of the Court and counsel, and we do not tread lightly in withdrawing our request. But at this point, we think it in everyone's best interest to focus on moving forward with the process and progressing our discovery review. Thank you for your time and careful consideration of these issues.

Respectfully submitted,

/s/ Lori G. Cohen

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Attorneys for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 5, 2020, I served the foregoing letter to the Court which was served on all counsel of record via filing in the CM/ECF system.

/s/ Steven M. Harkins